

REMARKS

All outstanding requirements will now be addressed in the order they appear in the Office Action mailed January 27, 2009.

Claim Rejections under 35 USC § 112

Claims 11, 26, and 30 stand rejected under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office action states that “[i]t is not understood what is intended by the phrase ‘essentially free’ of the crystal form. The basis on which the essential purity is based is not defined. It is also not understood how the purity is to be determined. If the reaction mixture is free of the β -crystal form as determined by X-ray powder diffraction, but not as determined by IR or DSC, or some other variation of these determinations, must the other forms of determination be also carried out?”

Applicants have amended claims 11, 26, and 30 to better define that the α -crystal form is free from the β -crystal form as determined by either X-ray powder diffraction or IR, i.e., either one of the spectroscopic methods can be used to determine whether the α -crystal form is free from the β -crystal form. Further, Applicants have specified that if X-ray powder diffraction is used to determine the absence of the β -crystal form, the X-ray powder diffraction spectrum does not contain peaks of relative intensity over 20% characteristic for the β -crystal form at the 20 angles of about 9.7, about 17.4, and about 19.9°, and if IR is used to determine the absence of the β -crystal form, the IR spectrum does not contain peaks characteristic for the β -crystal form of about 3336, 1656, 1596, and 1482 cm^{-1} . The claims now plainly require that only one of the two recited spectroscopic methods must be used, but both can be used to determine purity of the α -crystal form.

Accordingly, Applicants respectfully request withdrawal of the indefiniteness rejection with respect to claims 11, 26, and 30.

In light of the arguments and amendments presented above, Applicants respectfully request reconsideration and withdrawal of all 35 USC 112 rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 503182**.

Customer Number: **33,794**

Respectfully Submitted,

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